



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 25, 2018

David Chi  
Regulatory Affairs Manager  
Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, Missouri 63167

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Minor label changes including typographical corrections and change of the Alternate Brand Name from Bollgard® III to Bollgard® 3.  
Product Name: COT102 x MON 15985  
EPA Registration Number: 524-613  
Application Date: 01/11/2018  
OPP Decision Number: 538694

Dear Mr. Chi:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Additionally, the alternate brand name Bollgard® 3 has been added to the registration and the alternate brand name Bollgard® III has been removed from the registration. Our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or

Page 2 of 2

EPA Reg. No. 524-613

OPP Decision No. 538694

misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Matt Weiner by phone at 703-347-0333 or via email at [weiner.matthew@epa.gov](mailto:weiner.matthew@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a stylized flourish at the end.

Alan Reynolds, Team Leader  
Emerging Technologies Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure



**Plant-Incorporated Protectant Label**

**COT102 × MON 15985**

Insect-Protected Cotton  
(Alternate Brand Name: Bollgard® 3)  
(OECD Unique Identifier SYN-IR1Ø2-7 × MON-15985-7)

**Active Ingredients:**

*Bacillus thuringiensis* Vip3Aa19 protein and the genetic material necessary (vector pCOT1) for its production in event COT102 cotton (OECD Unique Identifier SYN-IR1Ø2-7).....≤ 0.00051%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary (vector PV-GHBK11) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7).....≤ 0.0540%\*

*Bacillus thuringiensis* Cry1Ac protein and the genetic material necessary (vector PV-GHBK04) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7).....≤ 0.00059%\*

**Other Ingredients:**

Hygromycin B phosphotransferase (APH4), marker protein, and the genetic material necessary (vector pCOT1) for its production in event COT102 cotton (OECD Unique Identifier SYN-IR1Ø2-7).....≤ 0.00007%\*

Neomycin phosphotransferase II (NPTII), marker protein, and the genetic material necessary (vector PV-GHBK04) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7).....≤ 0.00061%\*

β-glucuronidase protein (GUS), marker protein, and the genetic material necessary (vector PV-GHBK11) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7).....≤ 0.0066%\*

\* Percentage (wt/wt) on a dry weight basis.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Net (Contents) \_\_\_\_\_**

® Bollgard is a registered trademark of Monsanto Technology LLC.

**EPA Registration Number 524-613**  
**EPA Establishment Number 524-MO-002**  
Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, Missouri 63167

### **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *Kurstaki* (*B.t.*) delta endotoxins Cry1Ac, Cry2Ab2, and *Bacillus thuringiensis* (*B.t.*) Vip3Aa19 protein for the control of the following lepidopteran cotton insect pests:

This product controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following information:

1. The *B.t.* proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.* proteins is planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production, and insect-resistance management.
4. This product must not be planted nor sold for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, and south of Route 60 (near Tampa) in Florida.

The following information regarding test plots and seed production must be displayed on bags/bag tags of COT102 × MON 15985 cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within three miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of COT102 × MON 15985 cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within three miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of COT102 × MON 15985 cotton must employ one of the following structured refuge options:

#### 1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of this product (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to this product, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to this product. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the COT102 × MON 15985 fields.

#### 2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of this product (total of 100 acres). The variety of cotton planted in the refuge must be

comparable to this product especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to this product. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the COT102 × MON 15985 cotton fields.

### 3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of this product. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the COT102 × MON 15985 cotton. There is no field unit option.